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United States Court of Appeals
Tenth Circuit

DEC 26 2001

PATRICK FISHER
Clerk

PUBLISH

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

KAREN L. RALSTON, Plaintiff-Appellant, v. SMITH & NEPHEW RICHARDS, INC. aka Smith & Nephew North America, Defendant-Appellee	No. 00-3395

Appeal from the United States District Court
for the District of Kansas
(D.C. No. 98-CV-2174-GTV)

Submitted on the briefs:

Gary C. Haggerty and Frank A. Brancato of Brancato Haggerty & Palmentere L.C., Kansas City, Missouri, and Robert L. Wehrman of McDowell, Rice, Smith & Gaar, Kansas City, Missouri for Plaintiff-Appellant.

Peter von Gontard and Carl J. Geraci, St. Louis, Missouri, and Robert A. Henderson and Andrew M. DeMarea, Kansas City, Missouri for Defendant-Appellee.

Before **TACHA**, Chief Judge, **EBEL** and **GARTH**,[1] Circuit Judges

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GARTH, Circuit Judge

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[1] Honorable Leonard I. Garth, United States Circuit Judge, United States Court of Appeals for the Third Circuit, sitting by designation.

After examining the briefs and appellate record, this panel has determined unanimously to honor the parties' request for a decision on the briefs without oral argument. See Fed. R. App. P. 34(f). The case is therefore submitted without oral argument.

Plaintiff-appellant Karen Ralston appeals the district court's grant of summary judgment in favor of defendant-appellee Smith & Nephew, Inc. For the reasons discussed below, we will affirm the judgment.

I.

Ralston was diagnosed with cancer of her left femur in 1986. That year, she underwent a series of operations and procedures to treat her cancer, including six weeks of intensive preoperative radiation therapy, removal of bone tissue, and additional postoperative radiation. These treatments significantly reduced the strength of her left leg bone.

In April 1996, Ralston tripped and fractured portions of her lower left femur extending into the knee area. Ralston was treated by Dr. William Bohn, who implanted a multihole nail (the "MultiHole Nail") manufactured by Smith & Nephew in the broken femur. The purpose of the nail was to hold fractured bone fragments in the proper position to permit healing of the bone. According to Dr. Bohn's deposition testimony (discussed infra, see Section II.B.1), one advantage of the MultiHole Nail was its ability

to deal with multiple fractures, by binding *several* pieces of fractured bone in place for healing.

In October 1996, six and a half months after having the MultiHole Nail implanted, Ralston twisted her leg while at work, causing pain and weakness in her left leg. Upon examination, it was discovered that the MultiHole Nail had broken, and that another fracture was found in her left femur, although it was not the same fracture as had occurred before. Dr. Bohn performed a bone graft and removed the MultiHole Nail, replacing it with a longer titanium intramedullary nail that extended up Ralston's hip.

Ralston continued to have problems with her left leg, and in March 1998, Dr. Bohn performed another bone graft to relieve her continuing pain. He also referred Ralston to Dr. Howard Rosenthal, a physician specializing in oncologic orthopedics. Upon examination, he concluded that the original fractures of April 1996 had not yet healed, but that the failure of the MultiHole Nail did not prevent that original fracture from healing. In June 1999, Dr. Kimberly Templeton, an orthopaedic surgeon and associate professor at the University of Kansas Medical School, performed a total knee replacement by removing the titanium nail and the fractured femur, and implanting a piece of metal with a hinge in their place.

In April 1998, Ralston filed suit against Smith & Nephew alleging (i) design defect, (ii) manufacturing defect, (iii) various FDA violations, and (iv) negligence, including a failure to warn. Morever, she claimed that Dr. Bohn, as her treating

physician, was not properly warned that another kind of nail manufactured by Smith & Nephew – a five hole nail (the "Five Hole Nail") – was more durable than the MultiHole Nail, and may have been more appropriately used.

In June and July 1999, Smith & Nephew filed its motion for summary judgment as well as a motion to strike Ralston's only expert at that time, Dr. Christopher Ramsay. In a hearing before the district court on September 27, 2000, Ralston's counsel agreed to Smith & Nephew's motion to strike Dr. Ramsay, substituting Dr. Templeton as their new expert. Moreover, counsel advised the court that Ralston would abandon her product defect and FDA claims, and pursue only the failure to warn cause of action. Consequently, the district court granted Ralston additional time to file a supplemental opposition to Smith & Nephew's summary judgment motion based on the "failure to warn" theory.

On October 6, 2000, Ralston filed her Supplemental Opposition, featuring excerpts from the September 1999 and October 1999 depositions of Dr. Templeton, as well as a new affidavit from Dr. Bohn dated October 3, 2000 (the "October 3rd Declaration"). This latter affidavit contradicted certain statements Dr. Bohn had made in an earlier deposition conducted in March 1999. In response, Smith & Nephew procured a second affidavit by Dr. Bohn dated October 11, 2000 (the "October 11th Declaration"), wherein he modified certain statements he made in the October 3rd Declaration.

A final hearing was held before the district court on November 7, 2000, after

which the court ruled in favor of Smith & Nephew, finding no material issue of fact as to the inadequacy of the warnings provided by Smith & Nephew. In so ruling, the district court excluded Dr. Templeton's testimony under Fed. R. Evid. 702 on the grounds that she was unqualified to render an opinion on the subject-matter of Ralston's theory, and because her opinions were not reliable under the principles set forth in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Moreover, the district court disregarded the October 3rd and October 11th Declarations of Dr. Bohn on the ground that they contradicted his prior deposition on March 19, 1999, and instead relied only on Dr. Bohn's deposition testimony.

II.

In this appeal, Ralston first challenges the district court's exclusion of Dr. Templeton's expert testimony and its disregard of Dr. Bohn's October 3rd and October 11th Declarations. The district court's decision to admit or exclude evidence generally, including expert testimony, is typically reviewed under an abuse of discretion standard. See Atlantic Richfield Co. v. Farm Credit Bank of Wichita, 226 F.3d 1138, 1163-64 (10th Cir. 2000); National Assoc. Of Professional Baseball Leagues, Inc. v. Very Minor Leagues, Inc., 223 F.3d 1143, 1152 (10th Cir. 2000). A district court abuses its discretion "when it renders an arbitrary, capricious, whimsical, or manifestly unreasonable judgment." Copier v. Smith & Wesson Corp., 138 F.3d 833, 838 (10th Cir. 1998) (internal

quotations omitted). "A trial court's decision will not be disturbed unless [this Court has] a definite and firm conviction that the [trial] court has made a clear error of judgment or exceeded the bounds of permissible choice in the circumstances." Beaird v. Seagate Tech., Inc., 145 F.3d 1159, 1164) (10th Cir.) (citation omitted), cert. denied, 525 U.S. 1054 (1998).

A.

Fed. R. Evid. 702 imposes upon the trial judge an important "gate-keeping" function with regard to the admissibility of expert opinions. See generally Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). In order to determine whether Dr. Templeton's expert opinion is admissible, the district court had to undergo a two-step analysis. First, the court had to determine whether Dr. Templeton, the expert, was qualified by "knowledge, skill, experience, training, or education" to render an opinion. See Fed. R. Evid. 702. Second, if Dr. Templeton was so qualified, the court had to determine whether her opinions were "reliable" under the principles set forth under Daubert, 509 U.S. 579, and Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137 (1999). Because we find that Dr. Templeton's testimony was properly excluded on the ground that she was unqualified, we have no need to address the reliability of her conclusions under Daubert.

Dr. Templeton herself admits that she is not an expert on intramedullary nailing.

Throughout her deposition testimony, she conceded several times that she knew little – if anything – about the subject. She admits that she has done no research with intramedullary nailing and that she was asked to testify in the Ralston litigation in order to opine on the subject of bone healing, not to discuss the adequacy of warnings.

> I do absolutely no research with intramedullary nailing. My expertise is in oncology and in this instance was to bring in expertise as far as the treatment or the healing and problems with healing of a radiated bone.

Deposition Transcript of Dr. Templeton at *150. She has never been published in any matter, and the two articles that were accepted for publication had nothing to do with intramedullary nailing. Indeed, Dr. Templeton admits to never having researched the MultiHole Nail at issue in this appeal. See id. at 143 ("I've not done any research specifically looking at this nail.").

Moreover, on the issue of the adequacy of warnings generally, Dr. Templeton testified that she had never drafted, nor has ever been asked to draft, a surgical technique or warning of a product of any kind. See id. at *62 (Q: "Have you drafted a warning that you think is appropriate for this particular device in this case?" A: "No. . . ." Q: "Have you ever been asked to draft a surgical technique or warnings for a product of any kind?" A: "No."). She also testified that she had never seen a warning for any device that was similar to the form in the warning provided by Smith & Nephew in its "Warnings and Precautions Page," noting instead that the only warnings she had ever observed were "very brief warning[s]" that "they'll put down at the bottom of the page." Id. at *63.

The only reason advanced by Ralston that Dr. Templeton is qualified to testify as an expert is because she is a board certified orthopaedic surgeon and is therefore entitled to rely upon general orthopaedic and surgical principles and concepts. Ralston cites Compton v. Subaru of America, Inc., 82 F.3d 1513, 1519-20 (10th Cir. 1996) in support of this proposition.[2]

Ralston's reliance upon Compton is misplaced. That case holds only that "[a]s long as an expert stays 'within the reasonable confines of his subject area,' our case law establishes 'a lack of specialization does not affect the admissibility of [the expert] opinion, but only its weight.'" Id. at 1520 (quoting Wheeler v. John Deere Co., 935 F.2d 1090, 110 (10th Cir. 1991)). The dispositive question becomes, therefore, whether the issue of the adequacy of the warning with regard to Smith & Nephew's intramedullary nail is "within the reasonable confines" of Dr. Templeton's subject area. As demonstrated by Dr. Templeton's own admissions discussed above, it is evident that the district court did not abuse its discretion in finding that intramedullary nailing was not within the reasonable confines of her subject area.

Moreover, Compton's citation to Wheeler v. John Deere for the precept that

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[2] The viability of Compton has been questioned generally by some district courts given the fact that it was based on the premise that a Daubert analysis was inapplicable to expert opinions not based on a particular methodology or technique. See, e.g., Alexander v. Smith & Nephew, PLC, 98 F.Supp.2d 1310, 1315 n.1 (N.D. Ok. 2000). That premise has since been rejected by Kumho, 526 U.S. at 141 (holding that district court's gatekeeping function "applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge.").

reliance upon general principles and concepts is sufficient for admissibility of expert testimony is itself questionable as Wheeler is a pre-Daubert opinion. While this Court has not had the occasion to discuss that particular issue, the district courts in this Circuit have held after Wheeler and Compton, and we agree, that merely possessing a medical degree is not sufficient to permit a physician to testify concerning any medical-related issue. See Alexander v. Smith & Nephew, 98 F.Supp.2d 1310, 1315 (N.D. Ok. 2000) ("[t]he simple possession of a medical degree is insufficient to qualify a physician to testify as to the advantage of a spinal fixation device, the medical causation of spine-related ailments, or the mechanical functioning of an orthopedic implantation device," and see n.2, supra); see also United States Surgical Corp. v. Orris, Inc., 983 F.Supp. 963, 967 (D. Kan. 1997).

Finally, the Compton court merely held that the trial court *did not* abuse its discretion when it *admitted* expert testimony based upon the expert's familiarity with general engineering principles and concepts. That is a far cry from suggesting that a district court *always* abuses its discretion when it *excludes* an expert who may have *some* marginal familiarity with general concepts in the relevant field.[3] Accordingly, our decision in Compton erects no bar to the District Court's exclusion of Dr. Templeton's testimony below.

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[3] Indeed, as already discussed, Dr. Templeton concedes she has no familiarity at all in the relevant field of intramedullary nailing.

Thus, the district court's determination that Dr. Templeton did not possess the requisite qualifications to render an expert opinion concerning the adequacy of the warnings with respect to the MultiHole Nail was not "'arbitrary, capricious, whimsical, or manifestly unreasonable'" so as to constitute an abuse of discretion. Copier v. Smith & Wesson Corp., 138 F.3d 833, 838 (10th Cir. 1998) (quoting FDIC v. Oldenburg, 34 F.3d 1529, 1555 (10th Cir. 1994)). On the contrary, as we have just pointed out, Dr. Templeton's lack of qualifications to testify to the issue of "warnings" is well supported in the record.[4]

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[4] Ralston also contends that she was not informed that Dr. Templeton's qualifications would be an issue at the November 2000 summary judgment hearing, suggesting that it was "unfair surprise" for the district court to have excluded Dr. Templeton's testimony at that time. This contention, however, is belied by the record. In Smith & Nephew's Reply to Ralston's Supplemental Opposition, an entire section is devoted to the argument that Dr. Templeton was not qualified to render an expert opinion regarding the sufficiency of a warning. See Smith & Nephew Reply to Plaintiff's Supplemental Memorandum in Opposition to Defendant's Motion for Summary Judgment at *36 (Section B, entitled "Dr. Kimberly Templeton is Not Qualified to Render an Expert Opinion Regarding the Sufficiency of Warnings"). This reply was filed on October 27, 2000, eleven days in advance of the November 7th hearing. As the purpose of the hearing was to discuss the issues raised in the parties' supplemental summary judgment papers, it is disingenuous for Plaintiff to now claim that she was unaware that Dr. Templeton's qualifications would be at issue at the hearing.

Nevertheless, Ralston bore the burden of demonstrating to the district court that Dr. Templeton was qualified to render an expert opinion. See, e.g., United States v. Williams, 95 F.3d 723, 792 (8th Cir. 1996), cert. denied, 519 U.S. 1082 (1997); Hollander v. Sandoz Pharmaceuticals Corp., 95 F.Supp.2d 1230, 1234 n. 8 (W.D. Ok. 2000) ("As the proponent of their medical experts' testimony, the plaintiffs have the burden of establishing its admissibility."); In re Breast Litigation, 11 F.Supp.2d 1217, 1222 (D. Colo. 1998) ("The Plaintiffs have the burden of proving that the testimony of their expert (continued...)

B.

Ralston further contends that the district court abused its discretion in refusing to consider the October 3, 2000 and October 11, 2000 declarations of Dr. Bohn. According to Ralston, these later-filed affidavits did not contradict Dr. Bohn's deposition testimony of March 1999. Moreover, Ralston argues that the affidavits were not "sham" affidavits, and therefore should not have been disregarded by the district court.

1. Contradictions in Dr. Bohn's Testimony

Notwithstanding Ralston's protestations to the contrary, our review of Dr. Bohn's March 1999 deposition testimony reveals a number of material contradictions in his subsequent sworn affidavits. First, Dr. Bohn clearly indicated at his deposition that he had reviewed the Surgical Technique Brochure (which contained several warnings concerning the MultiHole Nail), and that he had been satisfied with the information provided therein. The only question he had, according to his deposition testimony, was whether or not to fill all the holes in the nail.

> Q: And you reviewed that technique brochure?
> A: Right.
> Q: Were you satisfied with that information?

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[4](...continued)
witnesses is admissible pursuant to Fed.R.Evid. 702 and the standards set forth in Daubert."). Accordingly, Ralston cannot now complain that she was unprepared to attend to her burden and discuss her own expert's qualifications at the summary judgment proceeding.

A: Right. I mean it was basically there was no problem with it, as far as the — the only question I had is I reviewed that and later in surgery was — is one required to fill the holes. That was the only thing that I don't remember there being a definite yes or no you're required to fill all of those holes even if you don't, you know, have any purpose for the screw.

Deposition Transcript of Dr. Bohn at *24.

By contrast, in his October 3rd Declaration, Dr. Bohn claimed that he had never received *any* warnings from Smith & Nephew. See October 3rd Declaration at ¶¶ 3-4. Then, in the October 11th Declaration, Dr. Bohn stated that he did, in fact, receive "a Smith and Nephew supracondylar Nail surgical technique," that he "did review the technical details prior to Mrs. Ralston's April, 1996 operation," but that he simply does "*not recall* reviewing a WARNING page as it appear[ed] in the currently reviewed technical monograph." October 11th Declaration at ¶ 3 (emphasis added). He added that he could "not say whether or not a WARNING page existed in the material reviewed in 1996, only that [he] did not review it specifically." Id.

Second, Dr. Bohn testified at his deposition that he would not have used the Five Hole Nail in lieu of the MultiHole Nail even if he knew that the MultiHole Nail were less durable:

Q: At the time you selected the 12 millimeter multi-holed Smith & Nephew nail in April of '96, if you had known there was a five hole design of the same nail that didn't have holes through the length of the nail and was much more durable, would you have selected that nail instead?
A: Probably not, because of that additional fracture, the two fractures.

Deposition Transcript of Dr. Bohn at *55-56.

Accordingly, Dr. Bohn testified that durability was not a factor in using the MultiHole Nail, suggesting that his choice had to do with the ability of the MultiHole Nail to address the additional fracture in Ralston's leg. However, in his October 3rd Declaration, Dr. Bohn again contradicted his deposition testimony by stating "[a]t that time in the surgery, had I had the five-hole nail available to me and had I known of the significant durability advantage of the five-hole nail, I would have used the five-hole nail." October 3rd Declaration at ¶ 7.

In the October 11th Declaration, Dr. Bohn changed his position again, stating that "[t]he multihole nail was selected for its versatility in Karen Ralston's particular complex case in which there were two fractures. . . . I do not recall reviewing information about or having the 5 hole nail made available to me, nor did I have any reason to select that particular nail at the time." October 11th Declaration at ¶ 4.

Finally, Dr. Bohn emphasized at his deposition that Ralston's condition placed a great deal of stress on the MultiHole Nail, causing it to ultimately break under the strain, and that this failure — given the nature of Ralston's fractures — was inevitable.

> And so basically in that situation where you have a bone that's, you know, not solidly healed, you're just waiting for the pin or the rod to break. . . . I think to be fair, that's basically it. I think the rod broke under circumstances that you wouldn't expect it to in terms of a minor — basically I'm not sure there was any trauma at all and it broke. So one would guess that she had not had real good stress transfer across the fracture site and that there was still a lot of stress being borne by the rod and it couldn't take it and it just finally gave out. And to elaborate on that, I think it was doomed to happen. In other words, I was disappointed that it happened seven months post implantation, but we now know that it would

> have happened. It would have been 12 months or 18 months. It would have happened at some point.

Deposition Transcript of Dr. Bohn at *38.

In the October 3rd Declaration, however, Dr. Bohn painted quite a different picture by stating that "I anticipated the nail would serve its purpose for more than seven months and that the nail would have no trouble serving its purpose from twelve to eighteen months. . . . It is my professional opinion that a nail which is intended to be used to support a non-union bone to facilitate healing should last significantly longer than 7 months, especially when used in a patient, like Ms. Ralston, who weighs only 110 lbs. and is a very compliant patient." October 3rd Declaration at ¶ 5.

In the October 11th Declaration, Dr. Bohn changed his statement yet again by stating "[e]xcess stress occurred at that point in the bone and the nail both. The nail broke. The nail break was associated with a new fracture at the site of the prior fracture (same location, different line). If a nail of significantly higher fatigue strength had been selected, I am of the opinion that eventual failure of the device would have occurred because of the adverse condition of the healing of the patient's bone." October 11th Declaration at ¶ 7.

2. Sham Facts Issues

Contradictions found in a witness' testimony are not, in themselves, sufficient to preclude such testimony. Indeed, we have previously noted that "in determining whether

a material issue of fact exists, an affidavit may not be disregarded [merely] because it conflicts with the affiant's prior sworn statements." Franks v. Nimmo, 796 F.2d 1230, 1237 (10th Cir. 1986) (citing 10A C. Wright, A. Miller & M. Kane, Federal Practice & Procedure § 2738, at 473-74 (2d ed. 1983); 6 (Part 2) J. Moore & J. Wicker, Moore's Federal Practice ¶ 56.22[1], at 56-1325 to 56-1326 (1985 ed.)). However, we have also held that there are situations where a district court may be justified in disregarding certain contradictory testimony, noting that "courts will disregard a contrary affidavit when they conclude that it constitutes an attempt to create a *sham fact issue*." Franks, 796 F.2d at 1237 (emphasis added).

To determine whether a contradicting affidavit seeks to create a sham fact issue, we have looked to three factors: whether: "(1) the affiant was cross-examined during his earlier testimony; (2) the affiant had access to the pertinent evidence at the time of his earlier testimony or whether the affidavit was based on newly discovered evidence; and (3) the earlier testimony reflects confusion which the affidavit attempts to explain." Rios v. Bigler, 67 F.3d 1543, 1551 (10th Cir. 1995).

Turning to these factors, Ralston does not – and, indeed, cannot – dispute that the record amply discloses that the district court did not abuse its discretion in excluding Dr. Bohn's declarations of October 3rd and October 11th. There is no question that Dr. Bohn was cross-examined during his March 1999 deposition; that he had access to the pertinent evidence at the time of his deposition; and that there was nothing in the earlier deposition

testimony reflecting any level of confusion or uncertainty concerning Dr. Bohn's testimony requiring clarification or explanation. Moreover, the October 3rd Declaration came into existence more than a year and a half after Dr. Bohn's March 1999 deposition, and *only after* Ralston's counsel had abandoned all other claims and decided to focus only upon Ralston's "failure to warn" cause of action.

Given these circumstances, it is not an abuse of discretion to conclude – as the district court did – that these subsequent affidavits, which directly contradicted certain positions previously taken by Dr. Bohn and which were detrimental to Ralston's sole remaining cause of action, constituted those kinds of affidavits which fall within the ambit of creating a "*sham fact issue*." Consequently, the district court was entitled to rely on Dr. Bohn's March 1999 deposition testimony without regard to his later declarations in rendering its summary judgment ruling.

III.

Next, Ralston argues that the district court erred by granting summary judgment in favor of Smith & Nephew. This Court reviews the grant of summary judgment de novo, applying the same standard used by the court below. V-1 Oil Co. v. Means, 94 F.3d 1420, 1422 (10th Cir. 1996). "Summary judgment is appropriate only 'if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.'" Novell, Inc. v. Federal Ins. Co., 141 F.3d 983, 985 (10th Cir. 1998) (quoting Fed. R. Civ. P. 56(c)). "We examine the factual record and reasonable inferences therefrom in the light most favorable to the nonmoving party." Applied Genetics Int'l, Inc. v. First Affiliated Sec., Inc., 912 F.2d 1238, 1241 (10th Cir. 1990). If there is no genuine issue of material fact in dispute, we must determine whether the district court correctly applied the law." Novell, 141 F.3d at 985.

A.

Without the expert testimony of Dr. Templeton and the October 3rd and 11th Declarations of Dr. Bohn, we can discern no material issue of fact with regard to the adequacy of the warnings provided by Smith & Nephew in its Surgical Technique Brochure. Under Kansas law — which the parties concede applies in this diversity

action — a manufacturer's duty to warn consumers of foreseeable dangers can be summed up as follows:

> Ordinarily, a manufacturer has a duty under Kansas law to warn consumers and users of its products when it knows or has reason to know that its product is or is likely to be dangerous during normal use. The duty to warn is a continuous one, requiring the manufacturer to keep abreast of the current state of knowledge of its products as acquired through research, adverse reaction reports, scientific literature, and other available methods. A manufacturer's failure to adequately warn of its product's reasonably foreseeable dangers renders that product defective under the doctrine of strict liability.

Richter v. Limax International, Inc., 45 F.3d 1464, 1468 (10th Cir. 1995).

Kansas has adopted the "learned intermediary rule." Under that rule, the manufacturer's duty to warn its customers is satisfied when the prescribing physician is made aware of the risks and dangers of the product, since the patient cannot obtain the medical product except through the physician. See Humes v. Clinton, 792 P.2d 1032, 1039 (Kan. 1990). This doctrine has been described as follows:

> 'Where a product is available only through the services of a physician, the physician acts as a learned intermediary between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. . . . Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient. It has also been suggested that the rule is made necessary by the fact that it is ordinarily difficult for the manufacturer to communicate directly with the consumer.'

Id. at 1040 (quoting Terhune v. A.H. Robins Co., 577 P.2d 975, 978 (Wash. 1978)). Consequently, once it is determined that the manufacturer has delivered a warning to the treating physician with respect to the product at issue, the only remaining issue becomes whether the warnings were legally sufficient. Id. at 1043.

Here, the deposition testimony of Dr. Bohn indicates that he was provided with warnings in connection with the MultiHole Nail. Dr. Bohn testified that he read and was aware of the Surgical Technique Brochure, which itself contained the warnings concerning the MultiHole Nail. As discussed previously, he conceded that he was satisfied with the information in that brochure and that the only question he had was whether or not he should fill all the holes in the nail. Moreover, Ralston presents no evidence disputing the affidavit testimony of John Reabe, the Director of Regulatory Affairs for Smith & Nephew, who testified that every Surgical Technique Brochure included the document "Important Medical Information Warnings and Precautions," and that every "nail package" also included that document. Accordingly, the only issue remaining is whether the warnings contained in the Surgical Technique Brochure were adequate.

Under Kansas law, the standard for determining whether a warning is adequate is whether it is "'reasonable under the circumstances.'" Humes, 792 P.2d at 1043 (quoting Wooderson v. Ortho Pharmaceutical Corp., 681 P.2d 1038 (Kan.), cert. denied, 469 U.S. 965 (1984)). After careful and independent examination of the Surgical Technique

Brochure, it is evident that the warnings contained therein satisfy this standard.

First, the Warnings and Precautions page specifically warns of the risks in using the MultiHole Nail in patients with compromised conditions or pathologic fractures, such as Ralston's fracture. It states in bold type:

> **intramedullary nails are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for expended periods of time. All patients should be cautioned against significant weight bearing prior to good callus formation. For this reason, patients who are obese and/or noncompliant, as well as patients who could be predisposed to delayed or nonunions, must have auxiliary support.**

Surgical Technique Brochure at *500.

Second, under "contraindications," the Surgical Technique Brochure explicitly warns against the use of the MultiHole Nail in patients such as Ralston who have poor bone quality:

> **Contraindications**
> 1. Insufficient quantity or quality of bone, obiterated medullary canal, or conditions which tend to retard healing; also, blood supply limitations, previous infections, etc...

Id.

Finally, the Surgical Technique Brochure describes a variety of nails available for use by surgeons. The cover itself depicts the MultiHole Nail and the Five Hole Nail. Under "Design Features," the brochure specifically mentions both nails and their dimensions, and includes detailed diagrams pointing to structural differences between the two products. Id. at 63. It further instructs that "[t]he decision to use the [Five Hole

Nail] should be made based on fracture pattern and the degree of comminution. The Standard MultiHole Nail offers multiple options for screw placement *while the [Five Hole Nail] provides greater strength throughout the central portion of the nail*." Id. at 64 (emphasis added).[5]

Ralston contends that the warnings provided by Smith & Nephew are insufficient because: (1) there should have been more precise information discussing the degree to which the MultiHole Nail was weaker than the Five Hole Nail, (2) there was no warning stating that the MultiHole Nail would fail in a significantly shorter period of time than the eighteen months needed for Ralston's injuries to heal, and (3) Smith & Nephew failed to state that the MultiHole Nail should not have been used for bone fractures in a patient like Ralston.

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[5] Ralston also suggests that the district court abused its discretion when it declined to consider the so-called Voor Report on the basis that it lacked proper foundation. Ralston cites to the Voor Report for the sole proposition that Smith & Nephew was aware that the MultiHole Nail was significantly weaker than the Five Hole Nail. Ralston contends that a proper foundation was not lacking because the report was introduced in Dr. Rosenthal's deposition; it was relied upon by Dr. Templeton in her report; and it was relied upon by Dr. Bohn in his October 11th Declaration. Our difficulty with Ralston's argument, however, is that there was no linkage made to Smith & Nephew's knowledge. Indeed, any such linkage would be difficult because the Voor Report appears to have been published in 1997, sometime *after* Ralston's surgery and *after* the MultiHole Nail had already been implanted.

Even if the Voor Report were admissible, it would not change the ultimate resolution of this issue. Ralston refers to the Voor Report for the sole proposition that Smith & Nephew was aware of the fact that the MultiHole Nail was not as durable as the Five Hole Nail. As discussed below, the Surgical Technique Brochure contains a warning addressing this very issue.

Ralston's contentions, however, are belied by the content of the warnings described above. Those warnings reasonably warn that the MultiHole Nail is not as durable as the Five Hole Nail; that the MultiHole Nail is not intended to carry a significant amount of the weight of the patient; and that the nail should be guarded against being used in patients with poor bone quality. While Ralston prefers that these warning be more specific, Kansas law does not require that a warning warn against every conceivable risk under every conceivable circumstance. Rather, as already discussed, Kansas requires only that the warnings be "reasonable under the circumstances." Humes, 792 P.2d at 1043. Here, the warnings provided by Smith & Nephew reasonably cautioned against each of the specific risks alleged by Ralston.

In any event, as Ralston's contentions depend solely upon Dr. Templeton's testimony and Dr. Bohn's subsequent affidavits which, for reasons discussed above, were properly excluded, her claims lack evidentiary support and thus are insufficient to create a genuine issue of material fact.

B.

We have earlier observed that the only theory on which Ralston relied was her theory of an inadequate warning, and that the record fully supported the district court's summary judgment ruling that the warnings were legally sufficient. Moreover, we are satisfied that even were we to examine the record to reach the issue of causation – an

issue not implicated in the "failure to warn" theory that was decided by the district court – a failure to warn about the MultiHole Nail could not have caused Ralston's injuries.[6] The record is undisputed to that effect.

Here, the record reveals that, as noted previously (see Section II.B.1, supra), Dr. Bohn conceded in his deposition that he would not have used the Five Hole Nail rather than the MultiHole Nail. He admitted that he would not have used the Five Hole Nail even with the knowledge that the MultiHole Nail was weaker. This testimony conclusively establishes that an effective warning concerning the durability of the MultiHole Nail – presuming that the warning provided by Smith & Nephew was not sufficient (which we have held it is) – would have made no difference in Dr. Bohn's decision to use the MultiHole Nail instead of the Five Hole Nail.

Moreover, Dr. Bohn conceded that the generally impoverished condition of Ralston's bone was the true cause behind Ralston's injuries in October 1996. In his deposition, Dr. Bohn testified that Ralston's bone had not healed completely in the time between the initial femur fracture in April 1996 and the second fracture several months

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[6] Once a warning is ruled to be adequate and sufficient, as we have ruled here, it is not necessary to delve into the issue of causation. It is only where there is an inadequate warning that a "presumption of causation" arises. See Richter, 45 F.3d at 1472 (quoting O'Gilvie v. International Playtex, Inc., 821 F.2d 1438, 1442 (10th Cir. 1987)). The "effect of this presumption is to place the burden on [defendant] to rebut it." Id. (citing Mason v. Texaco, Inc., 741 F.Supp. 1472, 1490 (D. Kan. 1990), aff'd and remanded by, 948 F.2d 1546 (10th Cir. 1991), cert. denied, 504 U.S. 910 (1992)); cf. Wooderson, 681 P.2d at 1057 (noting that the evidence presented by defendant was "insufficient to rebut the presumption" of causation from a deficient warning).

later in October. According to Dr. Bohn, Ralston's healthy bone tissue was unable to attach or grown onto the surrounding dead bone tissues. See Deposition Transcript of Dr. Bohn at *36-37. Because of this, Ralston's condition placed a great deal of stress on the MultiHole Nail, causing it to ultimately break under the strain, and that this failure — given the nature of Ralston's fractures — was inevitable. See id. at *38 ("[I]n that situation where you have a bone that's, you know, not solidly healed, you're just waiting for the pin or the rod to break. . . And to elaborate on that, I think it was doomed to happen.").

Dr. Rosenthal's undisputed testimony (one of Ralston's own treating physicians since 1998) further supports Dr. Bohn's testimony. Dr. Rosenthal testified that there was nothing about the failure of the MultiHole Nail that prevented Ralston's femur from healing. See Deposition of Dr. Rosenthal at * 34-35 ("Q: Was there anything about the failure of the original nail that has caused Ms. Ralston's femur not to go on to union at this point? A: I don't believe so."). He noted that on examination of Ralston's femur, he realized that the original fracture had not yet fully healed. Id. at *29 ("Q: Okay. Has Ms. — at the time you saw Ms. Ralston in July of 1998, had her bone healed? A: There was [sic] signs of healing but I don't think it was healed well enough to allow, for example, her to fully weight bear on it without some type of assistance . . ."). He also explained that if a patient's bone does not heal (as Ralston's did not), the implant will inevitably fail. See id. at *20-21 ("A: The only purposes for an implant such as a nail is to hold the

pieces of bone in the right position in order to get them to heal. . . . It doesn't promote it to heal. . . . Q: All right. What happens, however, if the patient's bone doesn't heal? A: Well, the whole concept and philosophy behind implants is we're dealing with a race against time. Either the bone is going to heal before the implant fails or the bone is not going to heal and the implant will fail.").

The uncontroverted testimony of Ralston's own witnesses – Dr. Bohn and Dr. Rosenthal – demonstrate that the weakened and poor condition of Ralston's leg prevented the proper healing of her bone, causing the implant to ultimately break under the added stress. Given this evidence, it is quite evident that any purported failure to warn on the part of Smith & Nephew could have not have caused Ralston's injuries in October 1996 or thereafter.

IV.

For the reasons discussed, we will AFFIRM the decision of the district court.